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RECORD OF ORAL HEARING

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* DAVID WALLACH, ANDREI KOVALENKO,
MARSHALL S. HORWITZ, and YONGAN LI

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Appeal No. 2010-006439
Application No. 10/761,370
Technology Center 1600

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Oral Hearing Held: July 21, 2011

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Before TONI SCHEINER, LORA GREEN, and STEPHEN WALSH,
*Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Thursday, July 21, 2011 commencing at 9:20 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Paula Lowery, Notary Public.

PROCEEDINGS

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THE USHER: Good morning. Calendar Number 64, Appeal Number 2010-006439, Mr. Roger L. Browdy.

JUDGE SCHEINER: Good morning, Mr. Browdy.

MR. BROWDY: Good morning.

JUDGE SCHEINER: You know the drill, 20 minutes.

MR. BROWDY: This is a one issue case, so I don't think it'll take 20 minutes to discuss it; but we'll see.

Basically, Applicant discovered a novel protein that's called RAP2. The parents already issued to the protein, and this is a divisional on the antibodies to that protein.

Now, the prior art is a known protein called FIP2. FIP2 has some sequence homology to RAP2.

In the C terminus, the Examiner says it has some 50 percent sequence homology; but if we look carefully at the sequences, there's only one area that had eight amino acids in a row that are identical.

There are two areas that have five amino acids in a row that are identical, and the rest there's not even five in a row that are identical. There are similar ones.

The Examiner says, well, there's no one prior art reference that suggests raising antibodies to FIP2 or that discloses raising antibodies to FIP2. The Examiner says as a secondary reference it shows that it would be obvious to raise antibodies to FIP2 for various reasons relating to FIP2.

The Examiner says for certain antibodies raised against FIP2 will include

antibodies that often bind to RAP2 because of the certain areas of homology that are present.

My response to that is twofold. Number one, I don't think that the Examiner has established a prima facie case of obviousness for those antibodies that do bind to RAP2. I'll discuss that in a second.

Secondly, even if the Examiner has established a prima facie case of obviousness, I think the unexpected result from my antibodies -- the specific subset of antibodies of FIP2 that may exist that also bind to RAP2, the unexpected properties rebut a prima facie case of obviousness.

JUDGE WALSH: Mr. Browdy, does it make sense to say that an antibody that binds to two different proteins is specific for either one of them?

MR. BROWDY: I think that the answer is yes. I could foresee a situation where an antibody raised against a polypeptide of one protein that binds to that identical region two different proteins can be said to be specific for both of them.

I don't think that the word specific necessarily means that it'll bind to one protein and only one protein in the world. I'll leave it at that.

JUDGE SCHEINER: So you're not saying that your claim excludes antibodies that would also bind with the prior art protein?

MR. BROWDY: Absolutely not. My claims are drawn to any antibody that binds to RAP2.

JUDGE SCHEINER: So why isn't that --

MR. BROWDY: They all have the common property. All my claimed antibodies have the common property of binding to RAP2. Now, if some of those antibodies -- not all of them -- if some of those antibodies also bind to

FIP2, I don't care. They may have other properties I don't know about.
JUDGE SCHEINER: I guess my question is I know we're not talking about anticipation here. We have an obviousness rejection. But I guess my question is why wouldn't those antibodies -- let's assume for the moment there is a reason for someone to make antibodies to those common residues of the prior art protein or to make antibodies to that entire prior art protein in some of those antibodies --
MR. BROWDY: May or may not bind to RAP2.
JUDGE SCHEINER: -- cross react to the two proteins.
Why wouldn't those antibodies meet the requirements of your claim since your claim doesn't exclude things that bind other proteins besides RAP2?
MR. BROWDY: I understand. The answer is that if such antibodies existed, and going back to the first part of my argument, we don't know that the overlapping portion is on the outside of the protein. We don't know that you could raise antibodies against that portion that will necessarily bind to RAP2. We don't know if that portion is on the interior or exterior of the RAP2 protein.
We don't know that if you raise antibodies against that area, or if you raise antibodies to the whole thing there's going to be any antibodies that necessarily bind to RAP2.
JUDGE SCHEINER: I see.
MR. BROWDY: And necessarily -- this is essentially an inherency rejection.
JUDGE WALSH: On that question about why that particular region would be on the exterior of the protein, I think the Examiner found that it was a

leucine zipper.
MR. BROWDY: I'm sorry?
JUDGE WALSH: That those residues were associated with a leucine zipper or structure. That seems to be something that would be accessible. If it was going to be functional, it would have to be accessible.
MR. BROWDY: The Examiner didn't cite any secondary reference that would support a prima facie obviousness rejection. He did not cite any supporting documentation which it's the Examiner's burden to establish a prima facie case.
To say that necessarily any overlapping area is going to be immunogenic and, necessarily, it's going to necessarily be not only immunogenic but on the exterior of the molecule of the RAP2, or on the exterior of the FIP2, so that antibodies would be raised against it we will also find to be other. We can conjecture, but for inherency it has to be certain. It must be inevitable.
JUDGE WALSH: Going back to your unexpected results position, I also see, I think some difficulty in reconciling the idea that an inherent feature could be the basis for an unexpected result. If we look at the usual principle of discovering a latent property of an antibody, for example, a latent property of the FIP2 antibodies might be that they bind RAP2.
So if discovering a latent property isn't enough for patentability, would it be correct to say, oh, it's an unexpected? That seems to be what the latent property would have been.
MR. BROWDY: Let me address right now the issue of whether it's rebutted, and after that question which also is the rest of my answer to your

question. First of all, let's treat as prior art all antibodies to FIP2. Only a fraction, if any, are also going to bind to RAP2.

I relate to the case of In re May. I don't think it's in my Brief. It's 574 F.2nd 1082, 197 USPQ 601 (CCPA, 1978), which was cited with approval in the en banq decision of In re Dillon.

It found that there was a claim compound that was prima facie structurally obvious to a prior art compound. The prior compound and the claimed compound shared the same property that the prior art has for his whole group of compounds.

But it was unexpectedly found that the novel compound not only had the property of the prior art, but also had another very important property that would not have been predicted, and that the prior art did not have.

In that case they said you have to weigh the expected versus the unexpected properties. If the importance of the unexpected property is great enough, that you've overcome a prima facie case of obviousness.

Here the small, small subset -- if any -- of the antibodies to FIP2 that also bind to RAP2 have an unexpected, although inherent, property of binding to RAP2. You can use it to isolate RAP2 from mixtures of RAP2 with other things.

So even though it is a latent property not of a specific prior art compound, the prior art compound includes ones that have this latent property, and ones that don't.

I'm only claiming the ones that have this latent property. You have to effectively select it. If you're making monoclonal antibodies, you could raise a thousand monoclonal antibodies and maybe only five of them, if any,

are going to have these patent properties.
Why would we consider that those specific ones that have what you call this latent property would be obvious when the prior art is an obviousness rejection, not an anticipation.
I think the answer might be the same if the prior art specifically said antibodies, but the fact is we have an obviousness rejection that can be rebutted with unexpected results.
I think the ability to bind RAP2 is one of the unexpected results. It's only available on those small subset of antibodies against the entire FIP2 protein, if any, that will also bind to RAP2.
JUDGE WALSH: Assuming for a moment that position applied to the claims to monoclonal antibodies is a good one. Does that argument also inure to Claim 1 which the Examiner argues is just a polyclonal preparation? That molecule is in there somewhere.
MR. BROWDY: But as I said in my Reply Brief, the claims call for an antibody specific for RAP2. If you have -- if polyclonal antibodies specific for RAP2 is one thing. A polyclonal antibody specific for FIP2 is another thing.
A polyclonal antibody specific to FIP2 doesn't fall within the scope of my claim because it is not in my polyclonal specific for RAP-2. It may have a very small residual possibility of binding to RAP-2 possibly.
But that very small residual binding to RAP2 does not make it (a) this polyclonal antibody that you've raised to FIP 2. It does not make it a polyclonal antibody specific to RAP2.
That being said, I'd be happy to get my monoclonal antibody claims.

JUDGE SCHEINER: Do you have anything further?
MR. BROWDY: Just to stress one more time, we don't even know if there will necessarily be any RAP2 protein in the polyclonal FIP2. We're assuming that there will be because there are certain areas of overlap; but they're very small areas of overlap.
The Examiner has not presented any evidence to make us believe that necessarily -- not based on probabilities and possibilities -- but necessarily, it will inherently have protein antibodies against RAP2. That also applies to the polyols.
JUDGE SCHEINER: Okay.
MR. BROWDY: That's all I have.
JUDGE SCHEINER: I think we understand your position. Thank you for coming in.
(Whereupon, the proceedings at 9:33 a.m. were concluded.)